Paper No. 74

Box Interferences
Filed by: Merits Panel
Mail Stop Interference
P.O. Box 1450
Alexandria, VA 22313-1450
Tel: 703-308-9797
Fax: 703-308-7952 or 53

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

RONALD GODISKA and PATRICK W. GRAY
Junior Party[1]

v.

HAODONG LI and GEORGE SEIBEL
Senior party[2]

Patent Interference No. 104,002

Final Hearing: August 19, 2003

FINAL DECISION

---

[1] Application No. 08/479,620, filed 06/07/95.

[2] Application No. 08/464,594, filed 06/05/95.

Interference 104,002

Before, PATE, ELLIS and LORIN, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

This interference involves a patent application of Godiska et al. (Godiska), Application No. 08/464,594 (the '594 Application), assigned to Icos Corporation, and an application of Li et al. (Li), Application No. 08/479,620 (the '620 Application), assigned to Human Genome Sciences, Inc. and SmithKline Beecham Corporation. Li is senior party by virtue of the June 5, 1995 filing date of the '620 Application.

I. Background

The subject matter at issue is directed to an isolated polynucleotide encoding a polypeptide having a specific amino acid sequence. Both parties agree that the polypeptide encodes a chemokine. Chemokines are said to be a family of small, soluble proteins, 70-100 amino acids in length, which activate and attract leukocytes (white blood cells) during an immune response. The chemokine described by the count is 93 amino acids in length and is secreted by macrophages. Li has denominated the polypeptide as human chemokine beta-13 (Ckβ-13); whereas, Godiska refers to it as macrophage-derived chemokine (MDC).

II. The Count

Count A is the sole count in the interference and reads as follows:

Count A:

(a) An isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having the amino acid sequence of residues 1 to 65 of (Li) SEQ ID NO:2;

OR

(b) an isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide having the amino acid sequence of residues 25 to 93 of (Godiska) SEQ ID NO:2;

OR

(c) the complement of (a) or (b).

The claims of the parties which correspond to Count A are:

Godiska: claims 1-12 and 17-20

Li: claims 21-52

Only Godiska filed a brief and was represented by counsel at final hearing.[3]

III. Issues

The only issue present for our decision is whether Godiska has established priority of invention over Li.

[3] Godiska's brief (Paper No. 67) will be referred to as GB. The Godiska record will be referred to as GR, followed by the appropriate page number. Similarly the exhibits will be referred to as GX, followed by the page number.

IV. Priority

It is well established that priority of invention is awarded to the first party to reduce an invention to practice, either actually or constructively, unless the opposing party can demonstrate that it was the first to conceive and that it exercised reasonable diligence in later reducing the invention to practice. Cooper v. Goldfarb, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998); Price v. Symsek, 988 F.2d 1187, 1190, 26 USPQ2d 1031, 1033 (Fed. Cir. 1993).

In some circumstances, the court has held that conception and reduction to practice occur simultaneously. Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d at 1206, 18 USPQ2d at 1021. Under this doctrine the court has found that with respect to a complex chemical compound, such as a gene, "[c]onception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. ... [W]hen an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated." Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d at 1206,18 USPQ2d at 1021.

To prove actual reduction to practice, the court recently held in Estee Lauder

v. L'Oreal, S.A., 129 F.3d 588, 592, 44 USPQ2d 1610, 1613 (Fed. Cir. 1997) that

> . . . an inventor must establish that he "'actually prepared the composition and knew it would work.'" Hahn v. Wong, 892 F.2d 1028, 1032, 13 USPQ2d 1313, 1317 (Fed. Cir. 1989) (quoting Mikus v. Wachtel [II], 542 F.2d 1157, 1159, 191 USPQ 571, 573 (CCPA 1976)); see also Burroughs Wellcome Co. v. Barr Lab., Inc., 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994) (reduction to practice requires "the discovery that an invention actually works" (emphasis added)): see also Standard Oil Co. (Indiana) v. Montedison, S.p.A., 494 F. Supp. 370, 206 USPQ 676 (D. Del. 1980), aff'd, 664 F.2d 356, 212 USPQ 327 (3d Cir. 1981) (reduction to practice requires a showing of three elements: (i) production of a composition of matter satisfying the limitations of the count, (ii) recognition of the composition of matter, and (iii) recognition of a specific practical utility for the composition).

Godiska, as the junior party, has the burden of proving their case for priority by a preponderance of the evidence. 37 C.F.R. § 1.657 (b). See also, Bosies v. Benedict, 27 F.3d 539, 541-42, 30 USPQ2d 1862, 1864 (Fed. Cir. 1994); Peeler v. Miller, 535 F.2d 647, 651 n.5, 190 USPQ 117, 120 n.5 (CCPA 1976); Linkow v. Linkow, 517 F.2d 1370, 1373, 186 USPQ 223, 225 (CCPA 1975).

Godiska argues that Dr. Godiska worked under the direction of Dr. Gray to isolate and characterize clones obtained from a human macrophage cDNA library. GB, p. 125. Godiska further argues that on December 12, 1994, Dr. Godiska gave several isolated clones from said library to Ms. Christa Wood, a research associate at Icos Corporation, for DNA sequence analysis. Id., p. 126; GR 121, para. 14. Ms. Wood sequenced the clones using an Applied biosystems automated DNA sequencer, model 373A, and gave the results to Dr. Godiska on December 15, 1994. Id., p. 127; GR 75, para. 55; GR 122, para. 16. Dr. Godiska is said to have analyzed the three potential

reading frames of one clone, Mϕ390-2 (a.k.a. MO390-2 or mc13241) and found that only one [reading frame] had no stop codons. Id. Drs. Gray and Godiska are said to have "immediately recognized" that the continuous open reading frame of the Mϕ390-2 clone encoded a chemokine based on (i) the similarity of the amino acid sequence with those of other known chemokines; and (ii) the presence of a pair of cysteines near the amino terminus of the protein. Id., p. 128. When the Mϕ390-2 sequence was compared with other sequences that had been reported in the public GenBank database, the greatest sequence identity found was with a rat chemokine known as MIP-1β. Id.; GB, p. 60, Material Fact 133; GR 75, para. 55.

With respect to the "practical utility" of the polynucleotide of the count, Godiska argues that from January 30 to February 1, 1995, Dr. Godiska cloned and "PCR-amplified" the cDNA fragment encoding the mature chemokine 390 (a.k.a. MDC). GB, p. 134; GB, p. 72, Material Fact 156. Godiska further argues that from February 3-8, 1995, Dr. Godiska gave the "PCR-amplified" 390 DNA to Ms. Linda Watson, manager of the Histology laboratory at Icos Corporation, to make probes for use in an in situ hybridization experiment. GB, p. 135; GB, p. 72, Material Fact 158. Ms. Watson is said to have prepared antisense and sense probes to measure the expression of the 390 gene in selected normal and diseased tissues.[4] GB, p. 135; GB, p. 73, Material Fact 159. Ms. Watson radiolabeled the probes and performed

[4] The antisense probe is said to bind specifically to chemokine 390 RNA in tissue samples; whereas, the sense probe is said to be a negative control. GB, p. 135; GB, p. 73, Material Fact 159.

hybridization assays with numerous tissue samples. GB, p. 135; GB, pp. 73-75; Material Facts 160-163. On March 3, 1995, Ms. Watson reported to Dr. Godiska that chemokine expression was detected in colon tissue from a Crohn's disease biopsy, but not in normal colon tissue. GB, p. 136; GB, p. 75, Material Facts 164-165. These data are said to indicate that the 390 gene could be used as a diagnostic probe to differentiate between healthy and diseased colon tissue. GB, p. 136.

With respect to the "practical utility" of the polypeptide of the count, Godiska argues that by January 10, 1995, Dr. Godiska expressed the pm390-12 clone, which contained the full-length sequence of the chemokine 390 (MDC), in mammalian cells. GB, p. 144. In February and March, 1995, Dr. Godiska is said to have performed a number of transmigration assays using the supernatant from the transformed mammalian cells.[5] Id. Dr. Godiska gave the cells which migrated in the assay to Ms. Linda Watson. Id., p. 145. Ms. Watson performed cell differential assays on February 20, March 3 and March 14, 1995, to determine the type of cell that migrated through the barrier in Dr. Godiska's transmigration assay. Id. On April 3, 1995, Dr. Godiska received a report from Ms. Watson suggesting that the chemokine stimulated chemotaxis of lymphocytes and also monocytes. GB, p. 145, Material Fact 241.

Li does not contest Godiska's arguments.

We find, based on the record, that Godiska has demonstrated, by a preponderance of the evidence, that it was the first to reduce the invention of the count

[5] The transmigration assay is said to measure the ability of the recombinant cytokine to promote chemotaxis of lymphocytes. GB, p. 144.

to practice. Cooper v. Goldfarb, 154 F.3d at 1327, 47 USPQ2d at 1901; Price v. Symsek, 988 F.2d at 1190, 26 USPQ2d at 1033.

As indicated above, the count is directed to a polynucleotide comprising a nucleotide sequence which encodes a polypeptide having a specific amino acid sequence; viz, amino acid residues 1 to 65 of Li SEQ ID NO:2, or amino acid residues 25 to 93 of Godiska SEQ ID NO:2, or the complement thereof. To that end, we point out that our appellate reviewing court has held that given the complex nature of nucleotide and amino acid sequences, conception does not occur until there has been a reduction to practice. See, e.g., Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d at 1206, 18 USPQ2d at 1613. That is, with respect to determining priority of invention of a gene, the court has held that conception and reduction to practice occur simultaneously. Id. We apply this rule of law to the case before us. Therefore, in order to demonstrate conception of an invention within the scope of the count, Godiska must provide evidence that its inventors envisioned both a nucleotide and an amino acid sequence having the specific chemical composition set forth in the count.

Here, we find that Godiska isolated and sequenced, inter alia, a polynucleotide comprising a nucleotide sequence which encodes amino acid residues 25 to 93 of Godiska SEQ ID NO:2 on December 15, 1994. On said date, Ms. Christa Wood gave Dr. Godiska the results of the nucleotide sequencing experiments she had performed on numerous cDNA clones isolated from a human macrophage cDNA library. GX 1037, pp. 98-110. However, on the facts of this case, the mere determination of the

polynucleotide and amino acid sequences of various clones, including the Mϕ390 clone (mc13241), is not sufficient to establish an actual reduction to practice. Rather, we find that Godiska must also demonstrate that its inventors recognized a specific practical utility for the nucleotide and/or amino acid sequence of the Mϕ390 clone.

We make this finding based on Godiska's statement that its inventor's had a general plan to randomly select and sequence clones from a human macrophage cDNA library. GB, p. 54, Material Fact 119; GX 1021, p. 95; GX 1012, p. 181. Godiska further stated that Drs. Gray and Godiska hoped to find novel genes which encoded proteins important to human immunological processes.[6] Id., Material Fact 121 (Dr. Godiska wrote in his notebook that "Pat is seq'ing random Mϕ cDNA to find interesting genes"). Dr. Godiska is said to have randomly selected approximately 1000 macrophage clones for nucleotide sequencing, one of which was the Mϕ390 clone. GB, pp. 54-55, Material Fact 122. After sequencing the DNA, deducing the amino acid sequence, and comparing the Mϕ390 sequence with the sequences in the GenBank database, Dr. Godiska is said to have (i) noted that clone 390 encodes a "NOVEL CHEMOKINE"; and (ii) identified similarity between the Mϕ390 sequence and the rat chemokine MIP-1β sequence. GB, pp. 59-60, Material Facts 132-133; GX 1012, p. 181. However, even assuming, arguendo, that Dr. Godiska recognized the aforementioned characteristics of the polypeptide encoded by the Mϕ390 clone, we find such information does not establish a specific practical utility for either the

[6] Since Godiska's library was a cDNA library made from cellular mRNA, manifestly it comprised only those genes which are expressed in a cell.

polynucleotide or amino acid sequence of the Mϕ390 clone. Estee Lauder v. L'Oreal, S.A., 129 F.3d at 592, 44 USPQ2d at 1613.

We point out that Godiska states that

> Chemokines, also known as "intercines" and SIS cytokines," comprise a family of more than thirty small, secreted proteins (commonly 70-100 amino acids in length and 8-10 kiloDaltons in size ...) that attract and activate leukocytes (white blood cells) and thereby aid in the stimulation and regulation of the immune system. The name "chemokine" is derived from chemotactic cytokine, and refers to the ability of these proteins to stimulate chemotaxis (movement) of leukocytes. Indeed, chemokines as a group may comprise the main attractants for inflammatory cells into pathological tissues. The array of activities of any individual chemokine (e.g., the types of white blood cells that the chemokine attracts) generally is not identical to the array of activities of another chemokine. A chemokine may have attractant properties for more than one cell type, and may have other activities in addition to its chemoattractant activities. Conversely, a particular cell type may be influenced by more than one chemokine [emphasis added]. GB, pp. 47-48, Material Fact 106.

Thus, Godiska acknowledges that identifying a novel polypeptide as being structurally similar to other members of the chemokine family of compounds does not reveal its specific activity or utility. Estee Lauder v. L'Oreal, S.A., 129 F.3d at 592, 44 USPQ2d at 1613. That is, it appears that chemokines may attract inflammatory cells, but in any event the structure (amino acid composition) alone does not indicate which type of white blood cell it attracts. Nor does the amino acid composition of the chemokine reveal anything about how it "stimulates and regulates" the immune system.

In our view, Godiska's first recognition of a practical utility for the polynucleotide/amino acid sequence of the Mϕ390 clone occurred on March 3, 1995, when Dr. Godiska received the report from Ms. Watson as to the differential in situ hybridization results. GX 1013, p. 90; GX 1022, pp. 1-4; GR pp. 48-50, paras. 14-19.

These results indicate the usefulness of the polynucleotide sequence encoded by Mϕ390 in differentiating colon tissue of a Crohn's disease patient from normal colon tissue. Accordingly, we find that Godiska had an actual reduction to practice on March 3, 1995.

In view of our finding with respect to the polynucleotide sequence of the Mϕ390 clone, we need not reach Godiska's arguments with respect to the utility of the polypeptide having the amino acid sequence of residues 25 to 93 of Godiska's SEQ ID NO: 2.

Since Li is only entitled to its constructive reduction to practice date of June 15, 1995, we hold that Godiska prevails over Li with respect to priority.

V. Judgment

In view of the foregoing, judgment as to the subject matter of the count is hereby awarded to junior party RONALD GODISKA and PATRICK W. GRAY.

Accordingly, on the present record,

RONALD GODISKA and PATRICK W. GRAY are entitled to a patent containing claims 1-12 and 17-20, corresponding to the count; and

senior party, HAODONG LI and GEORGE SEIBEL, is a not entitled to a patent containing claims 21-52, corresponding to the count.

	)
William F. Pate, III	)
Administrative Patent Judge	)
	)
	)
	) BOARD OF PATENT
Joan Ellis	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
	)
Hubert C. Lorin	)
Administrative Patent Judge	)

Interference 104,002

Attorney for Godiska et al.:

Michael F. Borun.
Marshall, O'Toole, Gerstein,
Murray & Borun
6300 Sears Tower
233 South Wacker Dr.
Chicago, IL 60606-6402

Attorney for Li et al.:

Kenneth J. Meyers, Esq.
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
1300 I St., N.W., Ste. 700
Washington, DC 20005-3315